AMENDMENTS TO THE CLAIMS

The Listing of Claims replaces all prior versions of claims in the application.

Listing of Claims

1. (Previously presented) A stabilized immunostimulatory microparticulate complex comprising a cationic peptide immunogen wherein the peptide immunogen comprises a target B cell antigen or a CTL epitope and a T helper cell epitope and anionic CpG oligonucleotide wherein the cationic peptide immunogen has a net positive charge at a pH in the range of 5.0 to 8.0 calculated by assigning a +1 charge for each lysine (K), arginine (R) or histidine (H), a –1 charge for each aspartic acid (D) or glutamic acid (E) and a charge of 0 for all other amino acids in the peptide immunogen and wherein the anionic CpG oligonucleotide has a net negative charge at a pH in the range of 5.0-8.0 and is a single-stranded DNA comprising 8 to 64 nucleotide bases with a repeat of a cytosine-guanidine motif and the number of repeats of the CpG motif is in the range of 1 to 10.

2-3. (Cancelled)

4. (Previously presented) The immunostimulatory microparticulate complex of claim 1, wherein the cationic peptide immunogen is a mixture of synthetic peptide immunogens.

5. (Currently amended) The immunostimulatory microparticulate complex of claim 1, wherein the net positive charge of the cationic ~~synthetic~~ peptide immunogen is at least +2.

6. (Previously presented) The immunostimulatory microparticulate complex of claim 4, wherein the average net positive charge of the mixture of synthetic peptide immunogens is at least +2.

7. (Previously presented) The immunostimulatory microparticulate complex of claim 5 or 6, wherein the net negative charge of the anionic oligonucleotide is at least -2.

8. (Previously presented) The immunostimulatory microparticulate complex of claim 1, wherein the CpG oligonucleotide is a single-stranded DNA molecules with 18-48 nucleotide bases and the number of repeats of CpG motif therein in the range of 3 to 8.

9. (Previously presented) The immunostimulatory microparticulate complex of claim 1, wherein the CpG oligonucleotide has the formula: 5' X^1CGX^2 3' wherein C and G are unmethylated; and X^1 is selected from the group consisting of A (adenine), G (guanine) and T (thymine); and X^2 is C (cytosine) or T (thymine).

10. (Currently amended) The immunostimulatory microparticulate complex of claim 1, wherein the CpG oligonucleotide has the formula: 5'$(X^3)_2CG(X^4)_2$ 3' wherein C and G are unmethylated; and X^3 is ~~selected from the group consisting of~~ A or G; and X^4 is C or T.

11. (Cancelled)

12. (Previously presented) The immunostimulatory microparticulate complex of claim 1, wherein CpG oligonucleotide is selected from a group consisting of 5' TCG TCG TTT TGT CGT TTT GTC GTT TTG TCG TT 3' (CpG1) SEQ ID NO: 1, a 32 base length oligomer, and 5'nTC GTC GTT TTG TCG TTT TGT CGT T 3' (CpG2) SEQ ID NO: 2, a 24 base length oligomer plus an phosphorothioate group designated as n.

13. (Previously presented) The immunostimulatory microparticulate complex of claim 12, wherein CpG oligonucleotide is 5' TCG TCG TTT TGT CGT TTT GTC GTT TTG TCG TT 3' (CpG1) SEQ ID NO: 1.

14. (Withdrawn) The immunostimulatory microparticulate complex of claim 12, wherein CpG oligonucleotide is 5'nTC GTC GTT TTG TCG TTT TGT CGT T 3' (CpG2) SEQ ID NO: 2, a 24 base length oligomer plus a phosphorothioate group designated as n.

15. (Withdrawn) The immunostimulatory complex of claim 12, wherein the cationic peptide immunogen is a synthetic peptide derived from HIV CD4.

16. (Withdrawn) The immunostimulatory complex of claim 15, wherein the synthetic peptide derived from HIV CD4 is selected from the group consisting of SEQ ID NO:4, 5, and 6 and a mixture thereof.

17. (Withdrawn) The immunostimulatory complex of claim 16, wherein the mixture is a mixture of SEQ ID NO:4, 5, and 6.

18. (Previously presented) The immunostimulatory microparticulate complex of claim 12, wherein the cationic peptide immunogen is a synthetic peptide ~~is~~

conjugated to a T helper cell epitope.

19. (Previously presented) The immunostimulatory microparticulate complex of claim 18, wherein the cationic immunogen is selected from the group consisting of SEQ ID NO: 7, 8 and 9 and a mixture thereof.

20. (Withdrawn) The immunostimulatory microparticulate complex of claim 19, wherein the cationic immunogen is a mixture of SEQ ID NO: 7, 8, and 9.

21. (Withdrawn) The immunostimulatory complex of claim 12, wherein the cationic peptide immunogen is a synthetic peptide derived from IgE.

22. (Withdrawn) The immunostimulatory complex of claim 21, wherein the synthetic peptide derived from IgE is selected from the group consisting of SEQ ID NO:10 and 11 and a mixture thereof.

23. (Withdrawn) The immunostimulatory complex of claim 22, wherein the mixture is a mixture of SEQ ID NO:10, and 11.

24. (Withdrawn) A process for preparing a stabilized immunostimulatory complex according to claim 1 comprising the steps of:

(a) dissolving or dispersing the cationic peptide immunogen in an aqueous phase selected from the group consisting of distilled deionized water, saline, PBS and a mixture thereof with the proviso that the pH of the aqueous phase is lower than the ionization point of the peptide immunogen;

(b) Dissolving the anionic CpG oligonucleotide in an aqueous phase selected from the group consisting of distilled deionized water, saline, PBS and a mixture thereof;

(c) Adding the CpG oligonucleotide in the aqueous phase dropwise to the solution or dispersion of the cationic peptide immunogen in an amount to form a stabilized immunostimulatory complex of the peptide immunogen and the CpG oligonucleotide in a charge ratio of the cationic immunogen peptide to the CpG oligonucleotide in the range of 8:1 to 2:1.

25. (Withdrawn) The process of claim 24, further comprising the step of removing the aqueous phase of the suspension of the immunostimulatory complex obtained.

26. (Withdrawn) The process of claim 25, wherein the aqueous phase is

removed by lyophilization, or spray-drying.

27. (Withdrawn) The process of claim 24, wherein the immunostimulatory complex has an average particle size in the range of 1 to 50 μM.

28. (Withdrawn) The process according to claim 24 wherein the amount of the immunogen peptide and the CpG oligonucleotide added is in a charge ratio in the range of 8:1 to 1:1 of the cationic immunogen peptide to the CpG nucleotide.

29. (Withdrawn) The process according to claim 25 wherein the amount of the immunogen peptide and the CpG oligonucleotide added is in a charge ratio in the range of 8:1 to 1:1 of the cationic immunogen peptide to the CpG nucleotide.

30. (Withdrawn) The process according to claim 28 wherein the amount o f the immunogen peptide and the CpG oligonucleotide added is in a charge ratio in the range of 4:1 of the cationic immunogen peptide to the CpG nucleotide.

31. (Withdrawn) The process according to claim 29 wherein the amount of the immunogen peptide and the CpG oligonucleotide added is in a charge ratio in the range of 4:1 of the cationic immunogen peptide to the CpG nucleotide.

32. (Withdrawn) The process according to claim 28 wherein the amount of the cationic immunogen peptide and the CpG oligonucleotide added is in a charge ratio in the range of 2:1 of the cationic immunogen peptide to the CpG nucleotide.

33. (Withdrawn) The process according to claim 29 wherein the amount of the cationic immunogen peptide and the CpG oligonucleotide added is in a charge ratio in the range of 2:1 of the cationic immunogen peptide to the CpG nucleotide.

34. (Withdrawn) The process of claim 24 wherein the amount of the synthetic peptide used to form the immunostimulatory complex provides an excess of the peptide immunogen of between 10% and 90% by weight.

35. (Withdrawn) The process of claim 25 wherein the amount of the synthetic peptide used to form the immunostimulatory complex provides an excess of the peptide immunogen of between 10% and 90% by weight.

36. (Withdrawn) The process of claim 24 wherein the amount of the synthetic peptide used to form the immunostimulatory complex provides an excess of the anionic CpG oligonucleotide of between 10% and 90% by weight.

37. (Withdrawn) The process of claim 25 wherein the amount of the synthetic peptide used to form the immunostimulatory complex provides an excess of the anionic CpG oligonucleotide of between 10% and 90% by weight.

38. (Withdrawn) The process of claim 24 wherein the amount of the synthetic peptide used to form the immunostimulatory complex wherein there is less than 10% by weight of an excess of the cationic peptide immunogen and less than 10% by weight of an excess of anionic CpG oligonucleotide.

39. (Withdrawn) The process of claim 25 wherein the amount of the synthetic peptide used to form the immunostimulatory complex wherein there is less than 10% by weight of an excess of the cationic peptide immunogen and less than 10% by weight of an excess of anionic CpG oligonucleotide.

40. (Withdrawn) A process for preparing a water-in–oil emulsion comprising an immunostimulatory complex of claim 1, comprising the steps of:

(a) Preparing an immunostimulatory complex in aqueous phase selected from the group consisting of distilled deionized water, saline and phosphate buffered saline;

(b) Adding the immunostimulatory complex in the aqueous phase into a continuous oil phase selected from the group consisting of a synthetic oil, a vegetable oil, a mineral oil, a metablizable animal oil and a mixture thereof;

(c) Dispersing under mechanical shear the immunostimulatory complex in the aqueous phase into the continuous oil phase to form a homogeneous water-in-oil emulsion.

41. (Withdrawn) A process for preparing a water-in–oil emulsion according to claim 40, wherein step (c) comprises:

(a) Loading a first syringe with the aqueous phase containing an immunostimulatory complex;

(b) Loading a second syringe with the oil phase having an inherent viscosity of less than 1,500 mPa;

(c) Connecting the first and second syringes through a narrow bore tube to a membrane support housing a membrane of controlled pore size (0.05-20 □M);

(d) Extruding the aqueous phase into the oil phase by repeated exchanges

through the membrane until the homogeneous w/o-emulsion is formed.

42. (Withdrawn) The process of claim 40, wherein the oil phase is selected from the group consisting of a metabolizable or non-metabolizable oil or a mixture thereof.

43. (Withdrawn) The process of claim 41, wherein the oil phase is selected from the group consisting of a metabolizable or non-metabolizable oil or a mixture thereof.

44. (Withdrawn) The process of claim 43, wherein the oil phase is selected from the group consisting of Montanide ISA 720, Montanide ISA 51 or a mixture thereof.

45. (Withdrawn) The process of claim 44, wherein the oil phase is selected from the group consisting of Montanide ISA 720, Montanide ISA 51 or a mixture thereof.

46. (Withdrawn) The process of claim 40, wherein the aqueous phase may further comprise a surfactant, an emulsion stabilizer, or a combination thereof.

47. (Withdrawn) The process of claim 41, wherein the aqueous phase may further comprise a surfactant, an emulsion stabilizer, or a combination thereof.

48. (Withdrawn) The process of claim 46 wherein the aqueous phase comprises an emulsion stabilizer selected from the group consisting of a mannide-oleate and a derivative thereof.

49. (Withdrawn) The process of claim 47 wherein the aqueous phase comprises an emulsion stabilizer selected from the group consisting of a mannide-oleate and a derivative thereof.

50. (Withdrawn) The process of claim 40 wherein the oil phase comprises a further adjuvant selected from the group consisting of MPL, MDP, DDA, Avridine, BAY-1005, DC-Chol, Murapalmitine and mixtures or derivatives thereof.

51. (Withdrawn) The process of claim 41 wherein the oil phase comprises a further adjuvant selected from the group consisting of MPL, MDP, DDA, Avridine, BAY-1005, DC-Chol, Murapalmitine and mixtures or derivatives thereof.

52. (Withdrawn) The process of claim 40, wherein the aqueous phase

further comprises an aqueous soluble adjuvant selected from the group consisting of PCPP, saponins such as QS-21, Cholera Toxin, heat labile Enterotoxin from *E. Coli* and cytokines such as IL-2, IL-12, IFN-γ and mixtures and derivatives thereof.

53. (Withdrawn) The process of claim 41, wherein the aqueous phase further comprises an aqueous soluble adjuvant selected from the group consisting of PCPP, saponins such as QS-21, Cholera Toxin, heat labile Enterotoxin from *E. Coli* and cytokines such as IL-2, IL-12, IFN-γ and mixtures and derivatives thereof.

54. (Withdrawn) A process for preparing an in-situ gelling polymer comprising an immunostimulatory complex comprising the steps of:

(a) Preparing a suspension of the immunostimulatory complex in an aqueous solvent according to the process of claim 23;

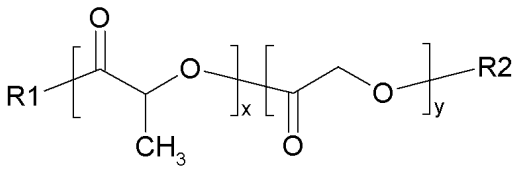
(b) Removing the water in the aqueous solvent from the suspension to obtain the immunostimulatory complex in dry form;

(c) Preparing a solution of an in-situ gelling polymer selected from the group consisting of poly-D,L-lactide-coglycolide copolymer, poly-D,L-lactic acid-co-glycolic acid copolymer, polycaprolactone, polyanhydride, polyorthoester, and poly(α-hydroxybutyric acid) in a biocompatible solvent selected from the group consisting of dimethyl sulfoxide (DSMO), N-methyl pyrrolidine (NMP), triacetin and glycerin;

(d) Reconstituting the immunostimulatory complex in dry form in the solution of the in-situ gelling polymer in the biocompatible solvent.

55. (Withdrawn) The process of claim 54 wherein in step (b) the water is removed by lyophilization.

56. (Withdrawn) The process of claim 54 wherein the biodegradable polymer is

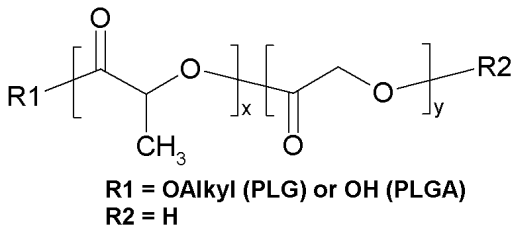


R1 = OAlkyl (PLG) or OH (PLGA)
R2 = H

wherein R1 is OH or alkoxy having 1 to 5 carbons and R2 is H; x:y is the ratio of each

monomer unit of the copolymer with x+y=1.

57. (Withdrawn) The process of claim 55 wherein said biodegradable polymer is



wherein R1 is OH or alkoxy having 1 to 5 carbons and R2 is H; x:y is the ratio of each monomer unit of the copolymer with x+y=1.

58. (Withdrawn) The process of claim 56 wherein the copolymer has a molecular weight in the range of 2,000-100,000 daltons and an inherent viscosity of 0.1-1.0 dl/g.

59. (Withdrawn) The process of claim 57 wherein the copolymer has a molecular weight in the range of 2,000-100,000 daltons and an inherent viscosity of 0.1-1.0 dl/g.

60. (Withdrawn) The process of claim 54 wherein the weight of the biodegradable in situ gelling polymer dissolved in the biocompatible solvent is in the range of 5 w/w% to 50 w/w%.

61. (Withdrawn) The process of claim 55 wherein the weight of the biodegradable in situ gelling polymer dissolved in the biocompatible solvent is in the range of 5 w/w% to 50 w/w%.

62. (Withdrawn) The process of claim 54, wherein step (c) further comprises dissolving a soluble adjuvant selected from the group consisting of PCPP, saponins such as QS-21, Cholera Toxin, heat labile Enterotoxin from *E. Coli* and cytokines such as IL-2, IL-12, IFN-γand mixtures and derivatives thereof in the biocompatible solvent.

63. (Withdrawn) The process of claim 55, wherein step (c) further comprises dissolving a soluble adjuvant selected from the group consisting of PCPP, saponins such as QS-21, Cholera Toxin, heat labile Enterotoxin from *E. Coli* and cytokines

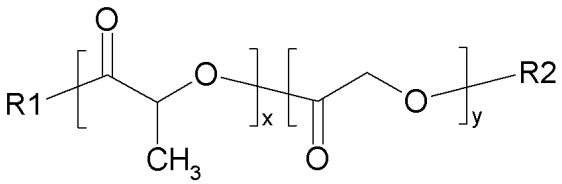
such as IL-2, IL-12, IFN-γ and mixtures and derivatives thereof in the biocompatible solvent.

64. (Withdrawn) A pharmaceutical composition comprising a suspension of an immunostimulatory complex of any one of claim 1 to 23 in an aqueous solvent selected from the group consisting of distilled deionized water, saline and phosphate buffered saline.

65. (Withdrawn) A pharmaceutical composition comprising a water-in-oil emulsion of an immunostimulatory complex of any one of claim 1 to 23.

66. (Withdrawn) A pharmaceutical composition comprising a gel of an immunostimulatory complex of any one of claim 1 to 23 wherein the gel is formed in situ by adding the immunostimulatory complex in dried form to a solution of an in-situ gelling biocompatible polymer selected from the group consisting of poly-D,L-lactide-coglycolide copolymer, poly-D,L-lactic acid-co-glycolic acid copolymer, polycaprolactone, polyanhydride, polyorthoester, and poly(α-hydroxybutyric acid) in a biocompatible solvent selected from the group consisting of dimethyl sulfoxide (DSMO), N-methyl pyrrolidine (NMP), triacetin and glycerin.

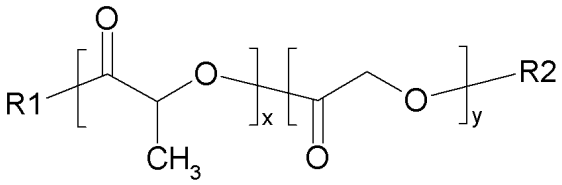
67. (Withdrawn) The pharmaceutical composition of claim 66 wherein the biodegradable polymer is



R1 = OAlkyl (PLG) or OH (PLGA)
R2 = H

wherein R1 is OH or alkoxy having 1 to 5 carbons and R2 is H; x:y is the ratio of each monomer unit of the copolymer with x+y=1.

68. (Withdrawn) The pharmaceutical composition of claim 67 wherein biodegradable polymer is



R1 = OAlkyl (PLG) or OH (PLGA)
R2 = H

wherein R1 is OH or alkoxy having 1 to 5 carbons and R2 is H; x:y is the ratio of each monomer unit of the copolymer with x+y=1, and wherein the polymer has a molecular weight in the range of 2,000-100,000 daltons and an inherent viscosity of 0.1-1.0 dl/g.

69. (Withdrawn) The pharmaceutical composition of claim 68 wherein the biocompatible solvent is DMSO.

70. (Withdrawn) A method of producing an immune response in a host comprising administering the composition of claim 64.

71. (Withdrawn) A method of producing an immune response in a host comprising administering the composition of claim 65.

72. (Withdrawn) A method of producing an immune response in a host comprising administering the composition of claim 66.

73. (Withdrawn) A method of producing an immune response in a host comprising administering the composition of claim 67.

74. (Withdrawn) A method of producing an immune response in a host comprising administering the composition of claim 68.

75. (Withdrawn) A method of producing an immune response in a host comprising administering the composition of claim 69.